K020522

IX. 510(k) Summary

MAR 21 2002

SUBMITTER:	DePuy AcroMed™, Inc. 325 Paramount Drive Raynham, MA 02767-0350 USA
CONTACT PERSON:	Karen F. Jurczak
DATE PREPARED:	February 15, 2002
PROPRIETARY NAME:	Surgical Titanium Mesh™ System
CLASSIFICATION NAME:	Implant, fixation device Spinal intervertebral body fixation orthosis device
PREDICATE DEVICE:	Surgical Titanium Mesh System (K003043) Surgical Dynamics Mesh Cage System (K003709)
INTENDED USE:	The Surgical Titanium Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Surgical Titanium Mesh System is also indicated for treating fractures of the thoracic and lumbar spine. The Surgical Titanium Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The Surgical Titanium Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Surgical Titanium Mesh System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX and Profile).
MATERIALS:	Commercially Pure (CP) Titanium Titanium alloy (Ti-6Al-4V)
PERFORMANCE DATA:	Biomechanical testing, including static axial compression and dynamic axial compression, were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Mr. Frank Maas
Regulatory Affairs Manager
DePuy Acromed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K020522
Trade Name: Surgical Titanium Mesh System
Regulation Number: 888.3060
Regulation Name: Vertebral Body Replacement Device
Class: II
Product Code: MQP
Dated: February 15, 2002
Received: February 19, 2002

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K020522

Device Name: Surgical Titanium Mesh™ System

Indications For Use:

The Surgical Titanium Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Surgical Titanium Mesh System is also indicated for treating fractures of the thoracic and lumbar spine.

The Surgical Titanium Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Surgical Titanium Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Surgical Titanium Mesh System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX and Profile).

for Mark N. Milkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020522

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)